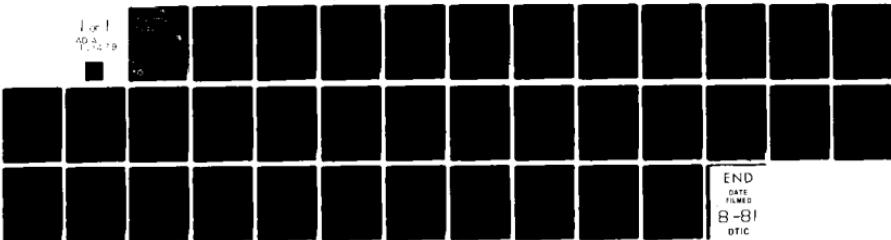


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BY THE U.S. GENERAL ACCOUNTING OFFICE

Report To The Administrator
Environmental Protection Agency

AD A 101479

EPA's New Research Controls:
Problems Remain.

Responding to past criticism of its research quality, the Environmental Protection Agency established new research control procedures in 1978. GAO's review of these new procedures indicates that although improvements have been made, more still needs to be done.

GAO recommends that EPA:

- Require that research strategies be developed.
- Establish procedures that require regulatory offices and researchers to agree before projects are started that the approach and timing are reasonable to meet intended needs.
- Improve its information systems to establish an adequate mechanism for monitoring projects.
- Monitor research progress against approved plans and strategies.
- Require external peer review of all research strategies and consistent peer review of extramural and inhouse research proposals.

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UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D.C. 20548

COMMUNITY AND ECONOMIC
DEVELOPMENT DIVISION

B-203649

The Honorable Anne M. Gorsuch
Administrator, Environmental
Protection Agency

Dear Ms. Gorsuch:

In response to past external and internal criticism, the Environmental Protection Agency has taken various steps to improve its research program. Our review of these new procedures and practices indicates that although progress has been made, more still needs to be done.

Our report contains recommendations to you on pages 20 and 29. As you know, section 236 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the House and Senate Committees on Government Operations not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report.

We are sending copies of this report today to the four committees mentioned above and interested legislative committees of both Houses; the Director, Office of Management and Budget; interested Members of Congress; and other parties.

We appreciate the cooperation and courtesy of EPA's staff during our review.

Sincerely yours,

Henry Eschwege
Henry Eschwege
Director

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GENERAL ACCOUNTING OFFICE
REPORT TO THE ADMINISTRATOR,
ENVIRONMENTAL PROTECTION
AGENCY

EPA'S NEW RESEARCH
CONTROLS:
PROBLEMS REMAIN

D I G E S T

External and internal criticism prompted the Environmental Protection Agency (EPA) to take a closer look at its research program. Consequently, in 1978, EPA started actions to improve research controls and acknowledged that its program lacked the following:

- A coherent research strategy that related program objectives and priorities to research activities.
- Effective communications and decisionmaking mechanisms between researchers and programs.
- Adequately responsive research results.
- An adequate program of long-term and anticipatory research.
- Consistent research quality.

GAO's review of EPA's new procedures and practices indicates that although progress has been made, more still needs to be done.

Because of the importance of research in EPA's regulatory mission, GAO evaluated the degree to which EPA took action to implement its new research controls and how these new procedures resolved previous research planning and management problems.

NEW RESEARCH CONTROLS ESTABLISHED

To enhance communications and develop a decision-making mechanism between researchers and program offices, EPA established 14 research committees comprised mostly of research management and program office staff. These committees are primarily responsible for (1) developing multiyear research strategies, (2) reviewing research plans, (3) participating in the development of research budget plans, and (4) reviewing the quality of ongoing and recently completed research. (See p. 3.)

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Additionally, EPA established a mandatory quality assurance and a long-term anticipatory research program. GAO did not assess these two programs because neither was in place long enough to gauge their effectiveness.

RESEARCH PLANNING IMPROVED:
BUT PROBLEMS REMAIN

Because of the new research committees, communications between researchers and users have improved and responsiveness of research findings to program needs is better than in the past. However, in many cases, the committees have not achieved agreement between researchers and the program offices concerning strategies and research to be performed.

Only three of the seven committees GAO reviewed had produced finalized and approved strategies; none were approved in time for the fiscal year 1982 budget. Draft and finalized strategies GAO reviewed varied greatly in scope, detail, and presentation of program office needs and planned research activity. (See p. 8.)

Relevance to program office needs of many currently planned research projects has been questioned by four of the seven research committees GAO reviewed, without satisfactory resolution. Committees have no authority to require solution of these problems, and researchers have little incentive to otherwise resolve them. Unless the groups formally agree that planned research will reasonably meet EPA's priority regulatory needs, criticism of EPA's research will continue. (See p. 11.)

MONITORING RESEARCH PROGRESS
AND PEER REVIEW OF RESEARCH
PROPOSALS NEED IMPROVEMENT

Monitoring the progress of research projects against approved plans and strategies is considered an integral step in assuring useful research results. Research committees need to be kept apprised of significant modifications in the conduct of planned research.

GAO found that none of the research committees it reviewed are performing this monitoring function. Of the seven research committees GAO reviewed, four do not intend to track projects. Three committees intend to monitor projects in the future using existing information systems. However,

GAO found these existing systems inadequate because they are either inoperative or do not contain sufficient data to effectively monitor projects. (See p. 21.)

EPA has been criticized in the past because of uneven research quality. Congressional hearings in 1976 and 1977, as well as studies completed by the National Academy of Sciences and the Office of Technology Assessment found this criticism valid. Assuring quality research is a difficult task, but generally accepted standards include peer review and publication of research results in scientific journals. EPA has made significant progress regarding peer review and publication of final research results, but more needs to be done. Five of the seven research strategies GAO reviewed were still not externally reviewed, and peer review of extramural and inhouse research proposals varied between laboratories. For example, of the four laboratories GAO reviewed, two required external peer review of their more significant inhouse research proposals while the remaining two only required internal review. (See p. 25.)

RECOMMENDATIONS

GAO recommends, that the Administrator, EPA:

- Require research committees to develop approved research strategy documents.
- Establish procedures that require regulatory offices and researchers to agree before projects are started that the approach and timing are reasonable to meet intended needs.
- Improve its information systems to establish an adequate mechanism for monitoring projects.
- Monitor research progress against approved plans and strategies.
- Require external peer review of all research strategies and consistent peer review of extramural and inhouse research proposals.

EPA's Office of Research and Development officials agreed with most of GAO's conclusions and recommendations. However, they disagreed with the recommendation that EPA establish procedures that require researchers and users to agree before work is started that the approach and timing of

projects are reasonable to meet intended needs. They said that general agreement on project outputs already exists and that a requirement for last minute approval of the approximately 1,800 new projects each year is tantamount to agreeing to what has previously been agreed upon. According to these officials, this would inevitably result in the slowdown of research programs, as well as a vast increase in bureaucratic papershuffling.

GAO disagrees. GAO found that agreement is not always reached concerning research project outputs and not all program offices are satisfied with the researchers degree of responsiveness to their expressed needs. Unless agreement is reached on the conduct, content, and timing of planned research, GAO believes untimely and less than useful research results will continue.

Concerning GAO's recommendations that EPA monitor research progress against approved plans and strategies, EPA officials said that they agree monitoring is necessary and that research committees should be encouraged to monitor research but felt that this monitoring should consist of only reviewing strategic research plans. They believe monitoring of implementation plans for specific projects should be the research manager's responsibility. These officials also agreed that specific users could be identified on EPA's various project monitoring reports, but would prefer that the various progress reports be distributed to specific users only on a request basis.

GAO continues to believe that research committees have a responsibility to monitor research progress and suggest corrections for significant deviations not only against approved strategies but also against implementation plans. GAO believes this is an integral step in assuring useful research results. Similarly, GAO believes EPA needs to distribute its project monitoring reports to specific users of the research results because individual users may not always be aware that a research project is underway to fulfill his or her needs. (See pp. 20 and 29-30.)

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ABBREVIATIONS

EPA	Environmental Protection Agency
GAO	General Accounting Office
ORD	Office of Research and Development
PTS	Project tracking system
SRI	Stanford Research Institute International

CHAPTER 1

INTRODUCTION

The Environmental Protection Agency (EPA) tries to abate and control pollution systematically by integrating a variety of research, monitoring, standard-setting, and enforcement activities. The primary mission of EPA's research arm, the Office of Research and Development (ORD), is to provide the scientific information that regulatory offices need to develop and enforce regulations. ORD is headed by an Assistant Administrator and organizationally is equal to EPA's major regulatory program offices. ORD manages more than 2,500 ongoing projects through six headquarters offices, two field administrative offices, one research information center, and 15 laboratories located through the country.

Excluding the construction grants program for publicly owned wastewater treatment facilities, approximately 30 percent of EPA's annual budget is earmarked for research and development. For fiscal year 1981, ORD was appropriated approximately \$253 million dollars to carry out its mission. Approximately 70 percent of ORD's appropriations is used for extramural research through contracts, grants and agreements primarily with universities, private commercial firms, nonprofit organizations, State and local governments, and other Federal agencies.

EPA research and development activities can be grouped into three basic categories:

- Short-term regulatory - responds to short-term or specific regulatory needs of the Congress or an EPA program or regional office.
- Long-term regulatory - addresses longer term program or regional office operational requirements but does not support immediately planned regulatory actions.
- Exploratory - conducted primarily for developing fundamental knowledge and principles to use in solving currently intractable problems or identifying or understanding future environmental problems for which no specific regulatory activity is currently contemplated.

PAST PROBLEMS WITH EPA RESEARCH

In his confirmation hearing before the Senate Committee on Environment and Public Works, the Deputy Administrator, EPA, testified that

*** *the need for research results that are immediately applicable to regulatory and enforcement issues has led in many instances to ill-conceived, poorly planned, and hurriedly executed studies which have resulted in products of inferior quality. This has culminated in a wasteful process, both in terms of time and EPA monies. It has also been costly to those being regulated and the credibility of the Agency has suffered as a consequence."

Congressional hearings in 1976 and 1977 also indicated that ORD was not satisfactorily identifying and fulfilling the Agency's needs for sound scientific information to support environmental regulatory decisions. Studies completed by the National Academy of Sciences and the Office of Technology Assessment reinforced this finding. These critics of EPA's research program attributed its lack of success to

- poor communication between ORD and the Agency's program offices,
- insufficient attention to long-term research, and
- lack of peer (experts inside and outside of EPA) review of research plans and results.

As a result of these criticisms, the Congress directed EPA to undertake a study of its research and development activities to determine the causes of and develop solutions for the problems facing the Agency.

EPA's NEW RESEARCH CONTROLS

In response to the congressional directives, EPA presented a report to the President and the Congress entitled "The Planning and Management of Research and Development Activities Within EPA" dated June 30, 1978, that outlined the steps EPA would take to correct its research problems. The report pointed out that EPA lacked the following fundamental components: (1) a coherent research strategy that related program objectives and priorities to research activities, (2) effective communications and decision-making mechanisms between researchers and program offices, (3) an adequate program of long-term and anticipatory research, (4) adequately responsive research results, and (5) consistent research quality. The report proposed the following corrective actions:

- 1) Identify distinct research planning units based on regulatory programs.
- 2) Establish permanent research committees for each research planning unit and a separate research oversight committee composed of EPA's top management.

- 3) Tie several planning and management processes to Agency-wide management processes with decisions focused on those connections.
- 4) Implement a research incentive system designed to assure responsiveness to program and regional research needs.
- 5) Incorporate peer review mechanisms throughout the planning and management process to improve research quality.

Research committees

In an attempt to enhance communications, EPA initiated a pilot project in 1978 to examine the feasibility of planning research and development programs by committees. The committees were comprised of representatives from ORD, program offices, and other primary organizational elements. Research committees were formed in five areas--drinking water, industrial wastewater, pesticides, mobile source air pollution, and particulate air pollution. Each committee was cochaired by a representative from ORD and from the appropriate corresponding program office. After the year-long pilot effort, EPA concluded that the committee system was not only feasible but that it had great potential for enhancing ORD's responsiveness to the program office's need for scientific information.

In a March 23, 1979, General Guidance for Research Committees, ORD integrated the committee framework into the Agency's mission by expanding the number of committees from 5 to 12. The particulate air pollution committee was expanded to encompass gaseous pollutants, and the following seven research committees were established: radiation, oxidants, hazardous air pollutants, municipal wastewater and spill prevention, water quality, solid waste, and testing and assessment. The guidance strongly encouraged EPA's Regional Office, Office of Enforcement, and Office of Planning and Management to designate representatives to accompany the ORD and program office cochairman and participants. Each committee was charged with five broad tasks:

- Review the current program to familiarize members with the status of ongoing work.
- Review the upcoming year's plans and formulate appropriate recommendations on improving those plans.
- Participate in developing budget year plans.
- Develop a multiyear research strategy with sufficient detail for use as a primary planning document in subsequent years.
- Review the quality of ongoing and recently completed research.

Two more research committees--energy and hazardous emergency response--were added in subsequent years, bringing the total to 14.

Research quality

As part of an attempt to offset criticism concerning the quality of EPA research, the Assistant Administrator for Research and Development issued a Peer Review Guidance on January 28, 1980. The guidance called for each laboratory to finalize plans for obtaining peer review of its research programs, projects, and research results.

These plans were to include provisions for

- ORD's senior laboratory management to encourage, when appropriate, the publication of research results in professional literature;
- peer review to be obtained for research results not published in professional literature;
- significant projects (those involving an expenditure above a predetermined level) to be reviewed by at least three non-EPA peers;
- projects not designated as significant to be reviewed during the annual laboratory program review by the cognizant Deputy Assistant Administrator; and
- non-EPA peers to be included whenever possible during the laboratory-level program reviews of ongoing research.

EPA also established a mandatory quality assurance program in June 1979 for all offices engaged in monitoring and measurement efforts. The program's two major objectives are to provide decisionmakers with

- a clear understanding of the quality of data for decisions and
- guidance and criteria for defining the quality of data for program implementation.

Exploratory research

The Congress responded to the criticism that EPA lacked an effective long-term exploratory research program by enacting Public Law 95-155, the Environmental Research, Development and Demonstration Authorization Act of 1978. Section 6(a) of the act required EPA to establish a continuing long-term research program. The law also required that a minimum of 15 percent of appropriated environmental research and development funds be allocated for long-term research. The Congress has included

similar provisions in EPA's research and development authorization acts for fiscal years 1979, 1980, and 1981.

In response to past criticisms and congressional mandates, EPA established an Office of Exploratory Research and initiated an institutional support program through exploratory research centers. The Office of Exploratory Research is responsible for, among other things,

- establishing an organization focal point for long-range research, identifying emerging problems, and developing programs in response to such problems;
- developing the capability for assessing emerging problems, their importance or impacts, and translating these needs into resource allocation decisions; and
- bringing together related basic research programs to maximize internal assessment and planning functions.

The exploratory research center program is designed to use institutions with well-established expertise in a specific area; these institutions will focus on long-term (3 to 5 years or longer) exploratory research to provide the link between basic and applied research, as it relates to EPA's missions. Seven centers have been established--three in fiscal year 1979 and four in fiscal year 1980. Because EPA is in the process of developing and modifying the various components of the exploratory research program, we believe it is too early for us to evaluate its activities.

OBJECTIVE, SCOPE, AND METHODOLOGY

The objective of this review was to determine the extent to which EPA is planning and performing research that is valid and useful in fulfilling the Agency's mission. We wanted to evaluate the degree to which EPA took action on its June 30, 1978, report to the President and the Congress in which it identified major problems and solutions for EPA's research planning and management.

Unless otherwise specified, this report deals with the approximately 85 percent of the ORD budget that does not constitute exploratory research.

We conducted our review at EPA headquarters and the following laboratories:

- Environmental Sciences Research Laboratory, Research Triangle Park, North Carolina;

- Health Effects Research Laboratory, Research Triangle Park, North Carolina;
- Health Effects Research Laboratory, Cincinnati, Ohio; and
- Municipal Environmental Research Laboratory, Cincinnati, Ohio.

These laboratories were selected because they represent the majority of research conducted for 5 of the 9 EPA program offices and 7 of the 14 research committees. Furthermore, the work conducted and managed at the selected laboratories comprises approximately 29 percent of the total EPA research budget for all 15 laboratories.

1981 ORD Expenditures

	<u>Extramural</u>	<u>Inhouse</u>	<u>Total</u>
	----- (thousands) -----		
Environmental Sciences Research Laboratory, N.C.	\$ 19,817.0	\$ 5,984.5	\$ 25,801.5
Health Effects Research Laboratory, N.C.	13,778.4	14,338.6	28,117.0
Health Effects Research Laboratory, Ohio	11,815.5	6,259.4	18,074.9
Municipal Environmental Research Laboratory, Ohio	<u>22,155.8</u>	<u>8,055.0</u>	<u>30,210.8</u>
Total for 4 laboratories	<u>\$ 67,566.7</u>	<u>\$ 34,637.5</u>	<u>\$102,204.2</u>
All EPA laboratories	\$250,835.7	\$103,592.9	\$354,428.6
Percent of total	27%	33%	29%

We interviewed persons in the following five program offices to obtain their views on research planning and management in EPA:

- Office of Air Quality Planning and Standards.
- Office of Drinking Water.
- Office of Mobile Source Air Pollution Control.
- Office of Water Program Operations.
- Office of Water Regulations and Standards.

We also discussed the research program with officials from the following seven research committees:

- Drinking water.
- Gases and particles.
- Hazardous air pollutants.
- Mobile sources.
- Municipal wastewater and spill prevention.
- Oxidants.
- Water quality.

We interviewed project officers, EPA and non-EPA researchers, and users of randomly selected research projects to better understand the communication process between ORD and its clients. We also examined documents, procedures, and practices pertaining to research committee operations and the peer review and quality assurance programs.

We interviewed officials in the following agencies to obtain their feelings about research quality and usefulness: the Food and Drug Administration, the National Academy of Sciences, the National Institute for Occupational Safety and Health, and the National Institute of Environmental Health Sciences. We also discussed procedures for assuring research quality with academicians from the University of Maryland and the University of Cincinnati and company officials from PEDCO Environmental, Inc., and ARMCO Steel and Kettering Laboratory in Cincinnati. We also discussed EPA research quality with the Automobile Manufacturers Association and the Environmental Defense Fund.

Finally, we discussed the matters contained in this report with ORD's Deputy Director, Office of Research Management and other ORD officials. Where appropriate, their comments have been incorporated in the final report.

CHAPTER 2
RESEARCH PLANNING HAS IMPROVED
BUT PROBLEMS REMAIN

Communications between research performers and users have improved and responsiveness of research findings to program needs is better than in the past due primarily to the establishment of research committees. However, despite these improvements, the research committees have not always been able to achieve agreement between ORD and the various program offices concerning research strategies and specific research projects to be performed.

Research strategies are intended to be a commitment between ORD and program offices that identifies and ranks research to be conducted over a period of several years. Although charged with developing such strategies, only three of the seven committees we reviewed had produced finalized and approved strategy documents. None were approved in time for the fiscal year 1982 budget cycle.

Disagreement about some currently planned research also continues. The relevance to program office needs of many currently planned research projects has been questioned by several research committees without satisfactory resolution. Committees have no authority to require solution of these problems, and ORD has little incentive to otherwise resolve them. Unless ORD and the program offices formally agree through the research committees that planned research will reasonably meet the Agency's priority regulatory needs, inferior and untimely research results may continue as a criticism of ORD research.

SLOW PROGRESS IN DEVELOPING
RESEARCH STRATEGIES

EPA has made significant strides in overcoming a lack of research strategy by instituting research committees and requiring that they annually develop research strategy documents. However, slowness in developing these strategy documents has hampered their effectiveness. Of the seven research committees we reviewed, none had produced strategy documents in time for the 1982 fiscal year budget cycle. Although some strategy documents have since been completed and others are in draft form, they vary greatly in scope, detail, and presentation of program offices research needs and ORD-planned activity.

Few completed strategies

Although some committees have successfully outlined program office needs and ORD's planned response over a short-term period, few have actually developed a comprehensive, long-term research strategy. Several ORD managers said that strategies are integral to any further discussions between researchers and program office users about the research that should be performed to fulfill

those strategy needs. They said that, without completed strategies, further discussions about the specific research to be performed were severely impeded, since there was no assurance that both groups had reached agreement on a common goal.

In March 1979 research committees were asked to have updated strategy documents available in time for the fiscal year 1982 budget preparation in the spring of 1980. Of the seven strategy documents we reviewed, only three received joint program office/ORD approval during 1980-81. None of those were completed in time for use in the budget process. As of April 1981, the remaining four committees still had not completed their strategies--three were in draft form while one was not developed in any usable form.

According to research committee officials, research planning disagreements between ORD and the program offices were the primary reasons strategies were not completed. Resolving these disagreements was hampered, according to these officials, because key personnel retired or resigned during the recent change of administration.

The Stanford Research Institute International (SRI) also identified problems in developing research strategies. In its December 1980 report 1/ SRI noted that the development of multi-year research strategies by research committees has been slow and those that have been developed do not effectively extend beyond 2 years because of such factors as the continuing need to prepare the next fiscal year's budget and the program offices' emphasis on immediate needs.

Varying scope and detail of strategy documents

While recognizing that committees should have appropriate flexibility in developing their strategies, the March 1979 General Guidance for research committees outlined the minimum requirements that should be satisfied in every document, including:

- Legislative mandate and authority.
- Regulatory, regional, and enforcement needs or requirements.
- ORD response to research requirements.
- Timetable and expected products.
- Resources for each year covered in the document.

1/"Health Effects Research and Standard Setting at EPA," SRI, Dec. 1980.

We reviewed seven research committee strategy documents (for those which had not been finalized we reviewed draft documents) and found that they varied greatly in scope, detail, and presentation of program office needs and ORD-planned activity. The documents varied in length from 21 pages (hazardous air pollutants draft) to 143 pages (drinking water).

Program offices' statements of need and ORD responses differ in scope and presentation from strategy to strategy. The drinking water strategy, for example, contains detailed program and regional office needs by contaminant and research area; it includes detailed laboratory by laboratory responses that specify individual projects and scheduled completion dates. At the other extreme, the hazardous air pollutants strategy document does not discuss specific program office needs but instead outlines general areas and uses of research to be performed.

The degree of long-term strategic planning varies greatly among these strategy documents. The water quality document, for example, contains a strategic outlook in the form of a 10-page section entitled "Projected Agency Policies and Priorities in the 1980's." Most other documents mainly dealt with research planning over a 1-3 year period with minimal input given to long-term planning. The draft oxidants strategy document, for example, represents an overview of the current ongoing research program with, in our opinion, no real strategic planning included.

In its January 1980 report entitled "Evaluation of Pilot Research Committees," EPA's Program Evaluation Division noted that research committees "must * * * begin to perform truly strategic research planning." The report notes that both short-term detailed planning and longer term strategic planning are important components of strategy documents. It states that the level of detail is important in that it fosters an understanding within ORD as to the explicit nature of the research needs of the program offices and allows them a greater degree of certainty as to the research being conducted by ORD. The report also recommends that the committees include strategic planning as a necessary major component of their research planning function.

The Science Advisory Board has also criticized EPA's strategic planning. The Board provides independent scientific and technical advice on numerous topics within the purview of EPA's regulation and research. In its assessment of the pesticides research strategy, the Board was critical of the effort put into the strategy. While noting that the use of the research committee structure resulted in greater coordination and cooperation between the Office of Pesticide Programs and ORD, the Board found that the strategy was poorly written and incomplete in that it did not sufficiently address several important areas of research. The Board also commented that errors of fact were numerous in the document and it lacked clarity and organization.

EPA has taken action that may improve the development of multiyear strategic planning in the future. In its April 1981 guidance for research committees, EPA requires that all committees prepare a 5-10 page multiyear strategy that will be used as a basis for formulating the fiscal year 1983 budget proposals. According to the acting director, program coordination staff, ORD, the committees can include more information in their documents if they desire; the 5-10 page requirements will only serve to standardize the basic strategy approach of all documents.

PROBLEMS IN PLANNING RESPONSIVE RESEARCH

Research committees are the only formalized structure for obtaining and communicating research user's needs to those who perform research. The research committee system is designed to assure that planned and ongoing research projects are consistent with approved strategy documents, are relevant to EPA's priority research needs, and will provide timely outputs for effective regulatory decisionmaking.

Our review of EPA's research planning process indicated that program offices were not always satisfied with planned or ongoing research. ORD treats research committee ideas, comments, and suggestions as advisory input only, with little direct incentive and no requirement to be responsive to these expressed needs. We found the following problems inhibit committee efforts to effectively plan responsive research:

- Communication between research users and ORD through the committee process has not always been effective in assuring that useful research projects and outputs will be performed.
- EPA has not implemented its plan to provide direct incentives to researchers to be responsive to regulatory needs.
- EPA has not established any mechanism requiring agreement before research is started that the approach and timing of planned projects are reasonable to meet intended needs.

Improved communications have not assured useful research

Strategy documents and laboratory output plans are EPA's mechanisms for communicating research needs and approaches. Shortcomings in their preparation and review can, however, prevent assurance that useful research projects and outputs will be performed.

Laboratory output plans are composed of two parts. Part one contains ORD guidance on the major research objectives,

major outputs, and expected completion dates. Part two is prepared by the laboratories and contains more specific information about the research area such as approach, rationale, completion dates, and outputs. Each research area may be comprised of as many as 15-20 related research projects. To further explain the major research areas, some laboratories were recently asked to prepare one-page descriptions for each research project. These summaries contain the title, objective, approach, rationale, resources, milestones, and laboratory contact for each project. This total package is then sent to the research committees for review.

Our review of the fiscal year 1981 research planning process indicated that the relevance of many currently planned and ongoing projects was questioned by several research committees without satisfactory resolution. Projects were questioned for

- lack of sufficient detail in ORD's plans to relate project objectives to program needs,
- incongruities between project size and priority and the planned ORD expenditures, and
- lack of defined interrelationships between planned and ongoing projects.

Still other questions were raised by research committees concerning vital regulatory needs that appear not to have been addressed by ORD's research plans. These concerns were not always resolved satisfactorily.

Of the seven research committees we reviewed, only two (water quality and drinking water) were satisfied that the committee process had produced laboratory output plans that would reasonably meet their research needs. The program office cochairman of the municipal wastewater and spill prevention research committee was comfortable with ORD's response to the committee's review comments. He believed the research committee structure has been very helpful in generating communication for research planning; however, he said that, to get specific research needs fulfilled, it continues to be a "case of who you know." The following summarizes the concerns expressed by the other four committees.

Gases and particles research committee

This committee's program office cochairman said that, as of February 26, 1981, the laboratory output plans had not been finalized. As a result, he did not know what projects were actually funded for fiscal year 1981 even though the fiscal year was almost half over. Part of the delay for fiscal year 1981 resulted from EPA not receiving its appropriation until December 1980. Still, as the program office cochairman noted, it is dif-

ficult for the program office to plan for fiscal year 1982 research work when it does not know what was approved for the prior year.

In reviewing this research area's draft laboratory output plans, the committee identified various problems. These included such matters as

- various inconsistencies and omissions, which make it unclear in many instances exactly what a research project would produce;
- lack of plans for certain program needs;
- limited usefulness of outputs in many cases; and
- many items that were not responsive to regulatory needs and schedules.

For example, one project that was given the highest priority rating by the research committee was never funded by ORD. The project would determine whether sulfur dioxide is a cocarcinogen in animals. The program office indicated that delaying this project for another year or two could mean that it will not be completed in time for the next sulfur dioxide standard review. This review is congressionally mandated and requires EPA to periodically assess the scientific validity of its standards.

The committee cochairman stated that he was not totally satisfied with ORD's response to his comments because very little change was made to the plans.

Oxidant research committee

As of February 17, 1981, this research area's laboratory output plan had not been finalized. Based on its review of the draft plans, the committee found

- some projects to be of low priority because they could duplicate other work or did not appear useful,
- certain project information was unclear, and
- several additional projects were not included but of interest to the program office.

For example, the program office committee cochairman recommended that ORD's project for developing a photochemical box model to measure ozone air quality be delayed, reduced, or cancelled. The committee stated that it has no plans at this time to use this model over the next several years. The laboratory, however, is undertaking the project in spite of the committee's opposition.

The committee cochairman said that he was not satisfied with ORD's responsiveness to the program office needs. He did say, however, that he believed ORD management was trying to do what it could, but he felt little change would occur to the plans because of budget restrictions. He said that research needs not addressed in fiscal year 1981 plans would probably be included in future years' plans to the extent possible.

Mobile source
research committees

Laboratory output plans for this research area were not finalized as of March 17, 1981. According to the program office committee cochairman, the draft plans did not satisfy all the program office needs. Six projects totaling \$1,387,000 were acceptable but 21 other projects with a proposed cost of \$7,255,600 were not. In many cases, the unapproved projects were wanted but the committee could not place them on the approved listing until a better description of what ORD was planning was submitted.

Some of the committee's other comments were that

- some projects were of low priority and should not be funded,
- approaches for conducting research generally were missing or lacked specificity, and
- objectives of some projects were not clearly stated.

The program office committee cochairman advised ORD of his concern that ORD may spend fiscal year 1981 mobile source funds for work not requested by the program office. He said that such action would result in a needless waste of Government funds. For example, the program office needed a brief evaluation of the real time particulate monitor developed by Ford and General Motors. The program office committee cochairman said that, since neither company seems confident that these monitors will be acceptable, the priority for this work should be low and the \$110,000 funding appears too high considering this project's priority. He also said that this work should be held in abeyance and will be approved later if funding permits after the entire plan is reviewed.

The program office committee cochairman was not satisfied with ORD's responsiveness to committee comments. He said that because of ORD's poor responsiveness, the program office had decreased resources committed to the research committee effort.

Hazardous air pollutants
research committee

Laboratory output plans for this area were finalized as of January 30, 1981. Although agreement was reached on many aspects

of the plan, the committee did identify some problems. It found that four projects rated as lower priority continue to receive funds although they are only marginally useful. For example, a project concerning bioassay support for identifying airborne carcinogens was rated as low priority but still is being conducted. The program office committee cochairman said that this work has also been performed at several sites and a final report on the findings is due soon. He said that after reviewing the final report and when better methods have been developed for collecting and analyzing gaseous samples, this type of study may merit higher priority.

The program office committee cochairman believes that budget restrictions also partially affected ORD's ability to be more responsive.

Research incentive system
short-lived

Researchers and regulators often disagree about the best way to satisfy EPA's research needs. Because of different professional perspectives based on experiences and demands on researchers and regulators, an inherent set of tensions is created, which results in complaints of unresponsive research results. To resolve this inherent dichotomy between researchers and regulators, EPA proposed to establish direct incentives to promote more responsive research by ORD. However, the incentive system was never implemented.

Differing research perspectives

Various studies have long recognized the inherent differences in perspectives between researchers and regulators. The December 1980 SRI study noted that

"communication between these two groups is made difficult by their different interests and emphasis: regulatory personnel are results-oriented and are less sensitive to the difficulties and time demands of research, whereas scientists are process-oriented and are less sensitive to providing specific results to meet deadlines."

In interviews with many ORD and program office staff members, we similarly found that researchers and regulators often differ substantially in their ideas on how best to satisfy EPA's research needs.

Although the National Academy of Sciences recognized similar differences in research perspectives, it concluded that "because EPA is primarily a regulatory agency with limited resources, the principal reason for its research must be to support decisionmaking."

Research incentive system

Recognizing this inherent dichotomy between the roles of researchers and regulators, EPA established a pilot research incentive system in March 1978 whereby a portion of the research funds would be allotted to program and regional offices rather than ORD. EPA believed this would establish a client/contractor relationship between researchers and regulators that would require them to work together to avoid unresponsive research results.

Under the system, program offices would identify research areas they believed they should more closely manage because those areas are key to the success of their regulatory efforts in the nearterm. These offices would then negotiate with ORD to conduct the needed research within its laboratories or to provide contract management services for the projects. Alternatively, the program offices, after consulting with ORD, could contract directly with outside firms to conduct the desired research. By allowing ORD to choose whether or not to "bid" on key projects, the system would allow ORD to set its prices competitively in order to develop inhouse research capability.

According to EPA, the system would provide a mechanism to encourage ORD to be responsive to regulatory research needs and encourage program and regional offices to take seriously their responsibilities for clearly articulating their research needs and for following the progress of key research projects. The intent of establishing a research incentive system was to enhance the impact of the research committee system in promoting openness and responsiveness in communications between research and program managers.

The system, however, was never funded, according to the chief of EPA's program evaluation branch in the Office of Planning and Evaluation. EPA decided not to implement the system because it believed that the research committee system is effectively promoting mutual understanding and responsiveness.

The system for resolving conflicts is inadequate

As originally established, each research committee had the responsibility for serving as the primary forum for resolving research issues encountered by the program offices, the regional offices, or ORD during the planning and implementation years. Realizing that total agreement on research to be performed may not be achieved within the research committee structure, in 1978 EPA proposed establishing the research oversight committee to resolve such disagreements. This committee, which was to be comprised of the EPA Assistant Administrators, never became operational. Instead, ORD established a research council comprised solely of ORD management to resolve planning disagreements.

According to the acting director of ORD's program coordination staff, the research council addresses general issues that affect ORD's overall operations. He told us that a program office cochairman whose specific research needs were not satisfied through the research committee system can appeal to his or her Assistant Administrator. The program office Assistant Administrator will then outline his or her concerns to the Assistant Administrator for Research and Development, who will make the final determination on the matter. In essence, research committee concerns about what research ORD should undertake are appealed to ORD management.

One research committee--mobile source--attempted to develop its own system for resolving research planning disagreements, but, according to its cochairman, ORD never adhered to the system. The system stipulated that whenever disagreements arose, the program office decisions would rule or control up to 80 percent of the funding for mobile source research and ORD laboratories would control the remaining 20 percent. This cochairman said that he would be satisfied with a 50-50 rule if ORD would honor it.

In its December 1980 report, SRI reported that although an appeal process has been articulated "it has never been used in the air research programs; the process has always reached a satisfactory adjudication at a lower level." The mobile sources committee cochairman questioned whether this was entirely accurate. He said that underlying the adjudication process are several factors. In addition to a hopeful wait-and-see attitude, program office committee cochairmen do not want to appear too negative about ORD's efforts to plan and produce responsive research, which has improved substantially. Also, because research committee comments are only advisory in nature and ORD has final authority over the research planned to be performed, appeals are not viewed by some cochairmen as effective ways of enhancing ORD/program office communication and cooperation.

Program office members of research committees we contacted agreed that ORD's responsiveness continues to depend heavily on informal relationships with ORD staff. Although they believe the research committee system has caused substantial improvements, they also told us that responsive research planning still has not been achieved in some instances and is highly questionable in others. The December 1980 SRI report stated that

"the mechanisms for this responsiveness appear to be informal rather than a formal consideration and decision by the relevant research committee."

Need to establish mechanism for requiring agreement on research plans

In its January 1980 report, EPA's Program Evaluation Division recommended that committees reach agreement on the content,

conduct, and timing of critical program-related research to the point that a client/contractor relationship between ORD and the program office is established. We made a similar recommendation in our October 1980 report entitled "Promising Changes Improve EPA's Extramural Research; More Changes Needed" (CED-81-6), which stated that the Administrator should:

"---Establish procedures that require regulatory offices and laboratories to agree before work is started that the approach and timing of research projects are reasonable to meet intended needs."

EPA disagreed with the recommendation. It stated that the jointly chaired research committees now perform project planning; their review of both the zero-based budget request and the laboratory output plans assure program office concurrence. It said that the regulatory offices can and do notify research committees when there is a shift in their needs, and adjustments are made by ORD. It said that project development, on the other hand, is the internal management prerogative of ORD's line managers. A requirement for last-minute approval of the approximately 1,800 new projects in a given year just before they are about to begin--presumably after all lengthy administrative work has been done--is tantamount to agreeing to what has previously been agreed upon; it is infeasible and managerially undesirable. This would inevitably result in the slowdown of research programs, as well as a vast increase in bureaucratic papershuffling.

We disagree with EPA's response to our recommendation. As discussed earlier, agreement is not always reached concerning the laboratory output plans and not all research committee cochairmen are satisfied with ORD's degree of responsiveness to their expressed needs. Unless agreement is reached on the conduct, content, and timing of planned research, we believe untimely and less than useful research results will continue.

In discussing this recommendation with selected ORD laboratory directors and research committee cochairmen and representatives, we were told that it would be reasonable to implement such a procedure for a portion of ORD's research budget but that agreement would probably not be reached on ORD's total planned expenditures in any given year.

Most program office cochairmen of research committees we contacted did not want total control of ORD's research budget; however, most did believe that, as a minimum, 50 percent of ORD's planned expenditures should be expressly ratified by the research committees before the research is started. Others believed 60 percent or more should be handled in this way. For example, a portion of EPA's research budget would be allocated to the research committee. This portion--say 50 to 60 percent of ORD's total research budget--would require express research committee agreement on the conduct, content, and timing of research projects before the work is started. Of the

remaining ORD budget, 15 percent or more would be used for the congressionally mandated anticipatory research. ORD would have final authority over the remaining research budget after considering the program offices' and research committees' comments and suggestions.

In its deliberations before passing Public Law 95-155, the Senate Committee on Environment and Public Works considered requiring that 60 percent of authorized research funds be earmarked for activities funded through the program offices rather than ORD. This action was not proposed by the committee nor subsequently acted on by Congress on the basis that EPA's top management had recently changed and was studying the problem of coordination with an intent to resolve it.

CONCLUSIONS

EPA has made significant strides in overcoming a lack of research strategy by instituting research committees and requiring them to annually develop strategy documents. However, slowness in developing these documents has hampered their effectiveness.

Without strategies, further discussions between ORD and the program offices about the specific research to be performed are severely impeded. Additionally, though some committees have been somewhat successful in outlining program office needs and ORD's planned response over a short-term period, few have actually developed a comprehensive long-term research strategy.

To assure that research strategies provide a programmatic context about which major goals and objectives can be identified, coherent plans developed and implemented, and results evaluated, all research committees need to annually develop finalized strategy documents. These documents should include both long-term strategic plans and the shorter term, more detailed look at program office needs and planned ORD responses.

Communications between ORD and program offices have improved, and responsiveness of research findings to program needs is better than in the past due primarily to the establishment of research committees. However, despite these improvements, the research committees in many cases have not been able to achieve agreement between ORD and the various program offices concerning research strategies and research to be performed.

Enhanced communication has not proven to be an effective measure for assuring useful research, although it is an integral part of the process. Researchers lack inherent incentives to be responsive to regulatory needs, and EPA has not fully implemented its plan to provide such incentives directly. Appealing decisions outside the committee structure without express authority is viewed by many as jeopardizing the improvements in communication and responsiveness that have been made.

If EPA is to maximize the use of its limited research budget, effectively provide scientific data on which to base its regulatory decisions, and assure useful research results, agreement on the conduct, content, and timing of research plans must be achieved on program-related research before work is started. This could be accomplished by various methods. The most prominently mentioned methods are (1) the research incentive system and (2) funding a substantial portion of research projects through research committees or program offices. Adopting either alternative could accomplish this objective.

RECOMMENDATIONS

We recommend that the Administrator of EPA

- require all research committees to develop approved strategy documents;
- require strategy documents to include both a long-term strategic outlook and a shorter term, more detailed, overview of program office needs and planned ORD responses; and
- establish procedures that require regulatory offices and laboratories to agree before projects are started that the approach and timing of research projects are reasonable to meet intended needs.

ORD COMMENTS AND OUR EVALUATION

ORD officials agreed with most of our conclusions and recommendations. They disagreed with our recommendation that EPA establish procedures that require regulatory offices and laboratories to agree before a project is started that the approach and timing of research projects are reasonable to meet intended needs. As discussed earlier (see p. 18), these officials continue to believe that general agreement on project outputs already exists and that a requirement for last-minute approval of the approximately 1,800 new projects each year is tantamount to agreeing to what has previously been agreed upon. According to these officials, this would inevitably result in a slowdown of research programs, as well as a vast increase in bureaucratic papershuffling.

We disagree. As discussed earlier, we found that agreement is not always reached concerning research project outputs and not all program offices are satisfied with the laboratory output plans and not all research committee cochairs are satisfied with ORD's degree of responsiveness to their expressed needs. We continue to believe that unless agreement is reached on the conduct, content, and timing of planned research, untimely and less than useful research results will continue.

CHAPTER 3

MONITORING RESEARCH PROGRESS

AND PEER REVIEW OF RESEARCH

PROPOSALS NEED IMPROVEMENT

According to a recent evaluation of research committees by EPA's Program Evaluation Division, monitoring the progress of research projects against approved plans and strategies is an integral step in assuring useful research results. The evaluation further states that research committees need to keep apprised of significant modifications in the conduct of planned research. We found, however, that none of the research committees we reviewed are currently monitoring research programs. Although three committees intend to monitor projects in the future using existing information systems, we found these systems inadequate mechanisms for effectively monitoring research.

EPA has been repeatedly criticized for its lack of quality research results. Responding to these criticisms, EPA made significant progress in assuring quality research by implementing an external peer review system and requiring research results to be published in professional journals. Despite these improvements, more needs to be done.

Additionally, EPA has established a mandatory quality assurance program. Although this program seems adequate, it is too early to gauge its effectiveness because it is not yet fully implemented.

INADEQUATE MONITORING OF

RESEARCH PROGRESS

Completing research as planned and delivering quality results on schedule are important measures of EPA's ability to achieve responsive research. Although research committees are responsible for monitoring research progress against approved strategies and plans, none of the committees we reviewed are performing this function. Some committees intend to monitor research projects in the future using existing ORD information systems. However, we found these systems are inadequate to effectively monitor research progress because they are either inoperative or do not contain sufficient data.

Research committees are not

monitoring research progress

Of the seven research committees we reviewed, none have been formally monitoring research progress. Three committees intend to develop monitoring systems in the future, but the four others do not intend to formally track projects. Rather, these four committees plan to rely on the existing informal mechanisms

to track projects. They plan to rely heavily on informal program office input to determine how well research is progressing toward meeting their needs.

Generally, research committee officials told us that they had not yet had the time to develop the appropriate mechanisms. They said that the majority of their efforts to date have been spent developing detailed research strategies, becoming aware of ongoing ORD research, and commenting on ORD's laboratory output plans.

Two studies have recognized the importance of monitoring research progress. SRI, in its December 1980 report, identified the lack of an effective monitoring system as a major problem. EPA's Planning and Evaluation Division, in its January 1980 report, stated that "the committees were not actively involved during their first year in overseeing the conduct of ORD research activities." This report further noted that one of the most important responsibilities of the committees in revitalizing the research planning system is their function in overseeing how planned research is implemented. We agree.

ORD information systems are
inadequate for monitoring research

Several ORD information systems are available to help research committees monitor research progress. These include the technical information plan, ORD progress reports, and the ORD Project Tracking System (PTS). We found, however, that these systems, as currently being used, do not provide adequate data to effectively monitor research.

Technical information plan

The technical information plan is intended to be a comprehensive listing of all outputs agreed to via the annual planning process. According to the senior management analyst in ORD's Technical Information Office, the system is designed to confirm the laboratories' interpretation of the final laboratory output plans. Specifically, it is intended to list the requestor, the type of research output, the laboratory involved, the project title, the project officer, and the report completion date.

The system cannot be used as a tracking system for all ongoing research because it includes only those projects expected to be completed and reported during the current fiscal year. No information is included concerning ongoing research with expected outputs in future fiscal years. For example, the technical information manager at one laboratory advised us that only 20 percent of his laboratory's ongoing projects are included in that laboratory's technical information plan.

Weaknesses in data content prevent the system from becoming an effective tracking tool. The system does not always list the specific research project's users and in some cases lists no

user at all. In addition, there needs to be some mechanism for informing both the research committees and the specific users of the research results of any significant deviations in the conduct of planned research. Of the 1,074 projects listed in the technical information plan for the four laboratories we reviewed 550, or 51 percent, had no individual user identified; 292, or 27 percent, had only a research committee or program office identified as the user; and only 208, or 19 percent, had a user name listed. Unless identified in the system, the individual user may not be aware that a research project is underway to fulfill his or her needs.

Recognizing these weaknesses, one program office--the Office of Air Quality Planning and Standards--is developing a second phase to the technical information plan. It involves designating a program office staff member to track research progress. The objective is to provide project tracking and ensure that reports are submitted on time and disseminated to the right program office individuals. The system also provides for feedback to the research committees on how well projects responded to regulatory needs.

Progress reports

Periodic progress reports are part of ORD's internal management reporting system. The content of the reports includes the project title and number, principal investigator, regulatory authority and program support areas, project objectives, milestones, and significant results. ORD has two types of progress reports--quarterly and monthly. The former is issued by laboratories every 3 months and includes an update of all ongoing projects. The latter is issued monthly but contains highlights of only selected ongoing projects. Neither quarterly nor monthly reports identify the specific user of the research results. Of the four laboratories we reviewed, two issue quarterly reports, one issues monthly reports, and one does not produce progress reports of any kind.

Another concern is that progress reports are not always distributed to the specific user at the program office nor is the specific user otherwise identified in the report. Without a specific user being identified in the report, it is difficult to determine what research is currently ongoing to fulfill the program office user's needs. For example, a user in the Office of Air Quality Planning and Standards told us that he saw progress reports on a grant project so infrequently that he had lost track of the project, which was started in December 1976. However, he said that he was still awaiting the final report and expected it to be marginally useful. Meanwhile, the ORD project officer had accepted the grantee's draft of the final report on November 7, 1979, as fulfilling the grant requirements. The report was filed, but not published by ORD. The project officer told us that he wanted to reanalyze and reformat some of the data presented in the draft report before publishing it, but he had not had a chance to do so as of March 1981.

We found that informal contacts and relationships with ORD staff have effectively kept many intended program office users aware of ORD's research progress. However, as noted above, this has not always happened. To effectively assure that users are aware of the research being performed for them, specific research users need to be routinely identified in ORD's progress reports.

ORD project tracking system

Another information system that could be used to monitor research is PTS. This system was developed in 1977 to be used as a management tool and information source for coordinating research projects. This system contains basic data on 4,600 individual ORD research projects, over 2,500 of which are ongoing. Under the PTS system, laboratories submit and update information for all ongoing extramural and inhouse research projects on a quarterly basis. This information is retained for 5 years after the project's completion. A PTS project printout includes the following data:

- Project title.
- Starting and completion dates.
- Inhouse or extramural effort.
- Prior, current, and future obligations.
- Project officer and telephone number.
- Investigators.
- Program title and legislative mandate.
- Results to date.
- Project status.
- Project abstract.

Theoretically, information users (in and outside of EPA) could call from anywhere in the country and, using lowspeed computer terminals, gain access to the data base. However, the PTS has not been operational since November 1980 due to administrative difficulties and project constraints. According to ORD's Office of Research Management's Deputy Director, EPA intends to reinstate the system in the future.

MORE IMPROVEMENT NEEDED
IN ASSURING QUALITY RESEARCH

EPA has been criticized in the past because of uneven research quality. Assuring research quality is a difficult task, but generally accepted standards of scientific quality include peer review, publication of research results in scientific journals, and a sound quality assurance program. Although publishing research results is no guarantee of high quality research, the greater the extent to which regulatory standards are based on published data, the more defensible such standards will be in subsequent litigation. A sound quality assurance program is regarded as the first and necessary criterion for assuring quality research. Responding to past criticisms, EPA established a program that provides for peer review and publication of research results and has also established a mandatory quality assurance program.

Although significant progress has been made regarding peer review and publication of final research results, we believe more needs to be done because

- all research strategies are still not externally reviewed and
- peer review of extramural and inhouse research proposals has been inconsistently applied.

The mandatory quality assurance program was not in place long enough to gauge its effectiveness; however, the planned program seems adequate.

Significant improvements made in
peer review and publication of
final research results

EPA has made significant improvements in peer reviewing and publishing final research results. All four laboratories we reviewed provide for journal publication of all final research results. In addition, two of these laboratories provide for external peer review of final products, and the remaining two provide for external peer review of significant or politically sensitive research.

Although important progress has been made regarding peer review and publication of final research results, we believe greater use of external peer review of research plans and proposals is still needed. A 1977 National Academy of Science

report 1/ similarly concluded that projects, as well as proposals, must be reviewed periodically to assure

--scientific and technical merit,

--relevance to scientific and technical program goals, and

--relevance of programs to EPA's mission.

Because the credibility of research performed by or for a regulatory agency is sometimes questioned, the Academy stated that EPA must take exceptional measures to assure that its results are scientifically valid.

Strategy documents are
not externally reviewed

In March 1979 EPA strongly encouraged research committees to seek external peer review of research strategies to gain different perspectives on the tasks before them. EPA also agreed with an earlier GAO report (CED-81-6, Oct. 28, 1980) that recommended that research committees be required to obtain peer review of their multiyear strategies. We found, however, that only 2 of 12 strategy documents for 1980-81 were subjected to external peer review; the Science Advisory Board reviewed the 1981 pesticides document and the 1980 drinking water document was reviewed by the National Drinking Water Advisory Council.

In January 1981 the Chairman of the Science Advisory Board recommended that the Board work with and provide advice on the preparation of EPA's research strategies. We believe such external peer review would enhance EPA's prospects of achieving a quality research program.

Peer review of research proposals
inconsistently applied

Major improvements in peer review procedures have been achieved regarding research grants and cooperative agreements. However, research proposals for contracts and inhouse projects are not always peer reviewed.

In 1977 the National Academy of Sciences stated that proposals should be reviewed to assure that the research plan is well formulated, that it has a reasonable chance to meet objectives, and that the researchers have adequate funds, facilities, and expertise to accomplish work. Reviews also minimize the risk of duplicating work already done elsewhere and may help to correct a limited or biased perspective.

1/ "Research and Development in the Environmental Protection Agency," National Academy of Sciences, 1977.

Additionally, the Academy stated that although EPA policy requires reviews of proposals from non-Federal sources, proposals from inside EPA and from other Federal agencies are not generally submitted for external review. It concluded that the scientific merit and credibility of EPA's scientific program would be enhanced by submitting all proposals for research, without exception, to peer review by scientists both inside and outside EPA.

ORD grants, cooperative agreements, and contracts

Extramural EPA research is conducted primarily through three methods--grants, cooperative agreements, and contracts. EPA requires all research proposals that will be formalized into grants and cooperative agreements to have external peer review. Of the four laboratories we reviewed, all required such peer review. However, EPA has not required contract proposals to be externally reviewed.

We found that research contract proposal peer review procedures are inconsistent between laboratories. Two laboratories require external peer review only for projects that exceed a certain dollar limitation (\$250,000 and \$100,000). Another laboratory provides for external peer review only upon the judgment of the project officer. The remaining laboratory provides for inhouse review only.

To guard against uneven quality research results, we believe EPA needs to require all laboratories to subject significant contract proposals (preferably those over \$100,000) to external peer review.

Inhouse research proposals

Although approximately 29 percent--\$103 million--of EPA's research budget is devoted to inhouse research, these research proposals are not consistently peer reviewed. Of the four laboratories we reviewed, two require external peer review of their more significant projects--those exceeding \$250,000 or two staff years of effort. The remaining two, however, only require internal review of their proposals.

Because inhouse research comprises such a large portion of EPA's research budget, these projects also need to be subjected to the rigors of external peer review.

EPA's planned quality assurance program seems adequate

EPA has conceded that, in the past, there has been a high degree of fragmentation, lack of coordination, poorly identified needs and resources, and duplication of efforts in its quality assurance procedures. For these reasons it established a mandatory quality assurance program in June 1979. All EPA

regional offices, program offices, laboratories, and those monitoring and measuring efforts supported through contracts or other formalized agreements are required to participate in the program.

The primary goal of the program is to ensure that all environmentally related measurements supported by EPA result in data of known quality. To meet this goal, the program provides for establishing and using a reliable monitoring and measurement system to obtain quality data to meet EPA's planned needs.

To implement this policy, each EPA laboratory, program office, and regional office was required to prepare a quality assurance plan covering all intramural and extramural monitoring and measurement activities. These plans include the overall policies, organization, objectives, and functional responsibilities designed to achieve data quality goals.

In addition, quality assurance project plans are required for each specific research project. These plans describe in more specific terms the quality assurance procedures for each project. They include such data as sampling and calibration procedures and internal quality control checks.

ORD's quality assurance management staff is primarily responsible for managing this program. Among other things, it

- reviews and approves quality assurance plans and
- conducts periodic reviews of EPA's quality assurance programs to determine if deficiencies exist and recommends corrective actions.

As of May 1, 1981, 27 of the 44 required quality assurance plans have been approved by the quality assurance management staff. The remainder are still in draft form. Also, as of May 1, 1981, the first series of quality assurance program audits were still being finalized.

Because EPA's quality assurance program is still being implemented, we believe it is too early to judge its effectiveness. However, based on our review of the program, it appears to adequately address the major past criticism of EPA's quality controls.

CONCLUSIONS

Research committees have the responsibility to monitor research progress against approved strategies and implementation plans and suggest corrections for significant deviations. Additionally, program office users of research results also need to be kept apprised of the research progress and have knowledge of any significant modifications in the conduct of planned research.

Although some research committees intend to formally monitor the progress of planned research, none of the committees we reviewed have done this to date. Some committees we reviewed intend to monitor research progress in the future using existing ORD information systems. However, we found these existing systems are either inadequate as effective mechanisms for monitoring research progress or were inoperative.

Although significant progress has been made regarding peer review and publication of final research results, we believe more needs to be done. Specifically, greater use of external peer review of research strategies and extramural and inhouse research proposals are needed.

EPA's new mandatory quality assurance program appears to adequately address past criticisms, but it is still too early to gauge its effectiveness.

RECOMMENDATIONS

We recommend that the Administrator of EPA:

- Require research committees to monitor research progress against strategies and implementation plans and ensure that research users are kept apprised of research progress.
- Require that the technical information plan include all ongoing research outputs agreed to via the research committee planning process, with the names of specific research users identified.
- Require ORD progress reports to identify specific research users for all program-related projects and require these reports to be distributed to the specific users.
- Reinstate the Project Tracking System to include the names of specific users for all program-related projects.
- Require external peer review of all research strategies and ensure consistent peer review of extramural and inhouse research proposals.

ORD COMMENTS AND OUR EVALUATION

ORD officials agreed with our conclusions and recommendations. They said that they agree monitoring is necessary and that research committees should be encouraged to monitor research, but felt that this monitoring should consist of only reviewing strategic research plans. They believe monitoring specific projects should be the principal responsibility of ORD managers. These officials did agree that specific users could be identified on EPA's various project monitoring reports but would prefer that these reports be distributed to specific users only on a request basis. We continue to believe that research committees have a

responsibility to monitor research progress and suggest corrections for significant deviations, not only against approved strategies but also against implementation plans. This is an integral step in assuring useful research results. Similarly, we believe EPA needs to distribute its project monitoring reports to specific users of research results, because individual users may not always be aware that a research project is underway to fulfill his or her needs.

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